Arizona Alzheimer's Consortium Meeting

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Agenda

- Introduction to the concept of collaborative IRB review
- Discussion of collaborative IRB review options and identification of potential consensus position
- Identification of other areas of collaborative work, including common contracting processes

Introduction to Collaborative IRB Review

National Efforts on Collaborative IRB Review

- Association of American Medical Colleges (AAMC) held conference in Nov. 2006 on alternative IRB models
  - Co-sponsored by NIH, OHRP, VA, AAMC, and the American Society of Clinical Oncology
  - Discussed perceived barriers to the use of alternative IRB models and suggested strategies for overcoming them
  - Links to the conference summary report and presentations can be accessed from the OHRP homepage at: http://www.hhs.gov/ohrp/ under Special Issues

AAMC Report

Benefits to collaborative IRB review:

- Avoiding inconsistencies in the consent process;
- Facilitating jointly sponsored training and educational activities;
- Conducting objective, nonbiased reviews free of local politics;
- Offering diverse reviewers with concentrated expertise in specialized areas;
- Eliminating duplication of effort;
- Stretching IRB resources;
- Increasing the efficiency and speed of review without sacrificing quality; and
- Stimulating collaboration and funding opportunities

FDA Efforts

- FDA guidance: "Using a Centralized IRB Review Process in Multicenter Clinical Trials" (March 2006)
  - http://www.fda.gov/cder/guidance/OC2005201fnl.htm or http://www.fda.gov/cder/guidance/OC2005201fnl.pdf

State Efforts

- Arizona Translational Resource Network (AzTransNet), sponsored by the Arizona Biomedical Research Commission (ABRC)
- Clinical and Translational Science Award (CTSA) Grant Application

Regulatory Compliance

- FDA and OHRP regulations permit reliance on an outside IRB
  - 45 CFR 46.114 ("With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.")
  - 21 CFR 56.114 ("institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.")

To rely on an outside IRB….

(1) Enter into agreement setting the terms of IRB review. Recommended terms in AAMC report:

- Division of responsibility for initial and continuing review
- Ability of Institution to reject research approved by IRB
- Method for IRB to understand local context
- Effective communication with investigators
- Responsibility for training
- Logistics and coordination
- Post-approval monitoring
- Incident investigations and reporting
- Responsibility for speaking to the media re "catastrophic untoward events"

To rely on an outside IRB….

(2) Both IRBs must have written procedures describing how they implement responsibilities under the agreement. Examples from FDA Guidance:

- How the institution's IRB determines that the central IRB is qualified to review research conducted at the institution
- How the central IRB intends to communicate with relevant institutions, the institutions' IRBs, and investigators regarding its review
- How the central IRB ensures that it provides meaningful consideration of relevant local factors
- How the central IRB assesses the ability of a geographically remote site to participate in a study (e.g., whether the site has medical services appropriate to the complexity of the study)

To rely on an outside IRB….

(3) Institution must amend its FWA to list the outside IRB

To rely on an outside IRB….

(4) The outside IRB must ensure that it addresses "local" issues in its review

- Sensitivity to community attitudes
- Ability to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice
- Meaningful consideration of various local factors in assessing research activities, including the cultural backgrounds (e.g., ethnicity, educational level, religious affiliations) of the population from which research subjects will be drawn, and community attitudes about the nature of the proposed research

Potential Concerns with Collaborative IRB Review

Legal Liability

- Concerns of delegating institution
- Concerns of hosting institution

Ways to minimize:

- Quality IRB—references; accreditation; experience with type of protocol
- Good communication between IRB and institution, particularly re: adverse events, protocol deviations, etc.
- Procedures for problem response: who decides when to investigate investigator noncompliance; who decides to suspend; when notice given to institutional official

Regulatory Liability

- Delegating institution remains responsible for review under OHRP regulations

Ways to minimize:

- Restrict scope of the FWA to apply only to federally-supported research, so that OHRP would not have jurisdiction over other research (particularly multi-site commercially sponsored studies)

Collaborative IRB Review Options

Potential Options

- Model 1: Creation of a new AAC IRB panel, involving representatives from each AAC Member
- Model 2: Designation of an AAC participant IRB(s) to review certain protocols or categories of protocols
- Model 3: Rotating IRB review between AAC participants
- Model 4: Delegation to outside IRB
- Model 5: Delegation to outside IRB with "local" IRB review
- Others?

Model 1: Creation of a new AAC IRB panel, involving representatives from each AAC Member

- Operational issues
  - How will members be appointed?
  - Where will the IRB panel meet?
  - How will investigators present to the panel?
  - Who will perform administrative functions?
  - How identify which protocols will be presented to the panel?
  - What are the likely costs?
  - Others?

Model 1: Creation of a new AAC IRB panel, involving representatives from each AAC Member

- Advantages of this model
  - Each participant will be invested in the new collaborative IRB review model
  - May avoid potential concerns about liability
- Disadvantages
  - Sharing of proprietary information (but may not be concern given IP disclosure provisions in the AAC Bylaws)
  - May result in slower IRB review for some AAC participants who presently have efficient IRBs
  - Difficulties in convening IRB members for meetings
  - Other concerns?

Model 2: Designation of an AAC participant IRB to review certain protocols or categories of protocols

- Methods for designating IRB?
  - If one IRB will be designated, which metrics examine?
  - If multiple IRBs will be designated, are there identified specialities within Alzheimer's research?

Model 2: Designation of an AAC participant IRB to review certain protocols or categories of protocols

- Operational issues
  - How identify which protocols will be presented to the panel?
  - How will investigators from other institutions present to the IRB?
  - How will the IRB be reimbursed for administration?
  - What are the likely costs?
  - Others?

Model 2: Designation of an AAC participant IRB to review certain protocols or categories of protocols

- Advantages
  - Uses already existing IRBs
  - Permits the Consortium to choose the most efficient IRB to increase productivity for all Members
- Disadvantages
  - Potential confusion among PIs re submission
  - Sharing of proprietary information with other AAC participants (but see Bylaws IP provision)
  - Potential concerns about liability?

Model 3: Rotating IRB review

- Operational issues
  - Will all IRBs participate?
  - How will reviewing IRB be identified?
  - How identify which protocols will be presented to the panel?
  - How will investigators from other institutions present to the IRB?
  - Who will perform administrative functions for the AAC?
  - How will the IRBs be reimbursed for administration?
  - What are the likely costs?
  - Others?

Model 3: Rotating IRB Review

- Advantages of this model
  - Each participant will be invested in the new collaborative IRB review model
  - Uses already existing IRBs
- Disadvantages
  - May create greater amount of bureaucracy
  - May cause confusion among PIs on protocol submission
  - Sharing of proprietary information with other AAC participants (but see Bylaws IP provision)
  - Potential concerns about liability?

Model 4: Delegate to Outside IRB

- Methods for designating IRB?
  - Which metrics to examine?
  - Issue RFP?

Model 4: Delegate to Outside IRB

- Operational issues
  - How identify which protocols will be presented to the panel?
  - Will the IRB be reimbursed collectively by the AAC or by each individual institution?
  - What are the likely costs?
  - Others?

Model 4: Delegate to Outside IRB

- Advantages of this model
  - Uses already existing IRBs
  - Avoids cost of creating new process for AAC
  - Permits the AAC to choose the most efficient IRB to increase productivity for all Members
- Disadvantages
  - Lack of local review
  - More expensive?
  - Potential concerns about liability?

Model 5: Delegate to Outside IRB with "Local" IRB Review

- Methods for designating IRB?
  - Which metrics to examine?
  - Issue RFP?

Model 4: Delegate to Outside IRB with "Local" IRB Review

- Operational issues
  - How identify which protocols will be presented to the panel?
  - Will the IRB be reimbursed collectively by the AAC or by each individual institution?
  - What are the likely costs?
  - Others?

Model 4: Delegate to Outside IRB with "Local" IRB Review

- Advantages of this model
  - Uses already existing IRBs
  - Avoids cost of creating new process for AAC
  - Permits the AAC to choose the most efficient IRB to increase productivity for all Members
- Disadvantages
  - More expensive?
  - Adds additional layer of review
  - Potential concerns about liability?

Which model will work best for the AAC?

Consider:

- Lower cost
- Avoidance of bureaucracy
- Less confusion for researchers
- Easier to administer
- Greater commitment by AAC participants
- Other factors?

Brainstorming on Other Collaborative Efforts

- Common contracting processes
  - Standardize CTA terms
  - Negotiate master agreements with pharmaceutical companies
    - Without budget terms; or
    - With budget terms
  - Others?
- Other collaborative activities?